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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,121	02/05/2004	Charmaine K. Harris	1023-270US02	3255

28863 7590 03/23/2006  
SHUMAKER & SIEFFERT, P. A.  
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ST. PAUL, MN 55125

EXAMINER
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ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/773,121

Applicant(s)

HARRIS ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/4/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments, see 9, filed December 7, 2005, with respect to the rejection(s) of claim(s) 1-43 under 35 U.S.C 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Mamo et al. (US 6,847,849) in view of DeWindt et al. (US 6,146,371).

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 1-43 stand and 44-45 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-43 of copending Application No. 10/718,038 (US Patent Publication 20050049663). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-15 and 44-50 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the stimulation lead" in line 6. There is insufficient antecedent basis for this limitation in the claim since the Applicant has not positively claimed the stimulation lead.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-22 and 24-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo et al. (US Patent Publication 20020147485 A1) in view of DeWindt et al. (US 6,146,371). Mamo et al. discloses a dilator with a conical distal tip and sheath as depicted in figures 8a-8c, in addition to a needle and a guide wire for application of neurostimulation therapy. "The needle is adapted to be withdrawn over the guide wire, and the dilator is adapted to be inserted over the guide wire proximal end to locate the guide wire within the dilator body lumen and to be advanced distally over the guide wire through the insertion path to dilate the insertion path to the dilator diameter" (page 2, paragraph 10). The process is displayed in figure 9a.

In addition, figure 9b "shows inserting and guiding a needle 36, e.g., a foramen needle 36, comprising a hollow needle body and a stylet or obturator 40 within the

needle body lumen, to the sacral nerve site in accordance with steps 50 and 52”(page 7, paragraph 98).

“The dilator body 47 is preferably conductive, and the dilator sheath 49 is preferably non-conductive but may bear radiopaque and visually observable depth marks 51 along its length to facilitate radiographic imaging when it is extended into the patient's body” (page 6, paragraph 91).

“The dilators 42 can be metal or plastic”(page 4, paragraph 74). Since the dilator, which includes both the dilator body and dilator sheath, can be constructed from plastic, the sheath and dilator are both deformable. In addition, according to Columbia University Press Dictionary, polyethylene is a “widely used plastic”. Therefore, since the dilator can be constructed from a plastic, it would have been obvious to create the dilator from polyethylene.

Mamo et al. discloses the claimed invention except for the oblong cross-section. DeWindt et al. (US 6,146,371) discloses an oval-shaped cardiac cannula, for the purpose of utilizes the space of the percutaneous aperture efficiently, thereby minimizing the necessary size of the access aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the dilator, dilator sheath and needle as taught by Mamo et al. with the oblong or oval cross-section as taught by DeWindt et al., in order to utilize available space more efficiently than the traditional round cannula.

The modified Mamo et al. discloses the claimed invention except for the specific values of the width and height of the sheath and dilator. It would have been obvious to

one having ordinary skill in the art at the time the invention was made to modify the dimensions of the sheath and dilator, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

2. Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Mamo et al., as applied to claims 1-22 and 24-45 above, in further view of Otten (US 5,255, 691). The modified Mamo et al. discloses the claimed invention except for the Tuohy needle. Otten teaches that it is known to utilize a Tuohy, for the purpose of accessing the epidural space of the spinal column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the needle as taught by the modified Mamo et al. with the Tuohy needle as taught by Otten, since it was known in the art to utilize Tuohy needles for introducing a guide wire or stylet into the body.

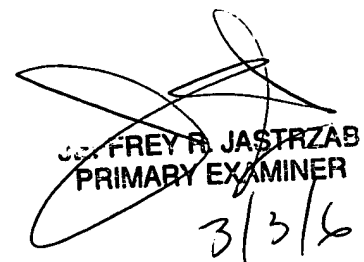
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alyssa M Alter  
Examiner  
Art Unit 3762



JEFFREY R. JASTRZAB  
PRIMARY EXAMINER  
3/3/6